

K042293

SEP - 8 2004

Philips Medical Systems Inc.
510(k) Summary

“Brilliance CT, Private Practice CV configuration” CT Scanner

1. Submitter

Philips Medical Systems (Cleveland), Inc.
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Cleveland, OH 44143
(440) 483-3000

Contact:

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595 Miner Road
Cleveland, OH 44143
Telephone: 440 483 3528
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Date of Summary: July 12, 2004

2. Device Name and Classification

Device Name: “Brilliance CT, Private Practice CV configuration” CT Scanner

Classification Name: Computed Tomography X-Ray System

The FDA has classified the Computed Tomography X-Ray System as
Class II in 21 CFR 892.1750 (Product Code 90JAK)

3. Device Description

The “Brilliance CT, Private Practice CV configuration” is a Computed Tomography X-Ray System featuring a continuously rotating X-ray tube and detectors, gantry, and multi-slice capability of up to 16 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the heart, cardiovascular, and peripheral vascular systems taken at different angles and planes. This device also includes signal analysis and display equipment, patient and equipment supports, components and accessories.

4. Intended Use Of The Device

The “Brilliance CT, Private Practice CV configuration” is a Computed Tomography X-Ray System intended to produce cross-sectional images of the heart, cardiovascular, and peripheral vascular systems by computer reconstruction of x-ray transmission data taken at different angles and planes.

5. Comparison to Predicate Devices

The “**Brilliance CT, Private Practice CV configuration**” CT scanner has the same technological characteristics such as design, material, and energy source as the predicate devices identified. In the opinion of Philips Medical Systems Inc., the “**Brilliance CT, Private Practice CV configuration**” CT scanner is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely:

- Brilliance CT (Philips Plus, K033326)
- Mx8000 IDT, K012009

6. Safety and Effectiveness Considerations

The safety of the device is assured by adherence to GMP practices and to International Standards. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures were adhered to, and test results demonstrate that the option specifications and functional requirements were met.

Material and Construction, as well as Electrical and Mechanical safety is assured by adherence to IEC 60601-1 standards and associated collateral and particular standards.

Radiation safety is assured by compliance with 21 CFR, Subchapter J performance standards.

Laser safety is assured by compliance to IEC 60625 standards

7. Substantial Equivalency Statement

Based on the above considerations, it is Philips’s opinion that the “**Brilliance CT, Private Practice CV configuration**” CT scanner is substantially equivalent in safety and effectiveness to the predicate devices, Brilliance CT 40 Slice configuration, K033326 and Mx8000 IDT, K012009.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems (Cleveland)
% Mr. Tamas Borsai
Program Manager,
Third Party Review Program
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K042293
Trade/Device Name: Brilliance CT, Private Practice
CV Configuration
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: August 17, 2004
Received: August 24, 2004

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act, or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

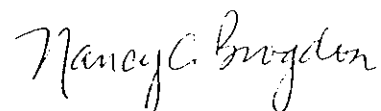
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 042293

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Device Name: "Brilliance CT, Private Practice CV configuration"

Indications for Use:

The Philips Brilliance CT in the Private Practice CV configuration is a Computed Tomography X-Ray System intended to produce images of the heart, cardiovascular (including pulmonary veins) and peripheral vascular systems (including the carotids, renals, aorta, iliac, and other distal vessels imaged by angiographic run-off procedures) by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories

Contraindications for Use:

The Philips Brilliance CT in the Private Practice CV Configuration is not indicated for imaging structures that are defined as non-cardiac and non-vascular (including soft tissue and bone).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

✓
Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042293